

**Maryland Board of Pharmacy
Public Minutes
December 20, 2006**

Officers Present: Mark Levi, President; Donald Taylor, Secretary; and Jeanne Furman, Treasurer

Commissioners Present: Cynthia Anderson, Margie Anne Bonnett, David Chason, Joseph DeMino, Harry Finke, Jr., Mayer Handelman, Alland Leandre, Michael Souranis, and Rodney Taylor

Board Staff Present: LaVerne Naesea, Executive Director; Patricia Gaither, Administrative and Public Support Manager; Shirley Costley, Licensing Manager; Anna Jeffers, Legislation and Regulations Manager; Colin Eversley, Compliance Investigator; Vanessa Thomas-Gray, Compliance Secretary; Alicia Carter, Secretary

Board Counsel: Linda Bethman

Guests: Mike Swarner, Target; Howard Schiff, MPhA; Georgette P. Zoltani, Division of Drug Control; Ron Nicholson, VetCentric; Arnold Clayman, MD-ASCP, Omnicare; John Clark, MSHP; Chris Wilburn, Jeffrey Brewer, MSHP, MPC; Scott Vehovic, Walgreens; Sue Uslin, Wal-Mart; Elizabeth Gernard, Wal-Mart; Raymond Love, University of Maryland; Michelle Andoll, Pharmacist; Gary Wirth, NACDS; Gil Genn, NACDS; Jeff Maltese, Melvin Rubin, Tony Tommasello, PEAC; Gil Cohen, PEAC; Daniel Ashby, Johns Hopkins, Cherokee Layson-Wolf

I. Introduction/Recusals – Members of the Board with a conflict of interest relating to any item on the agenda were asked to notify the Board at this time. There were no recusals.

II. Approval of Minutes November 20, 2006

Page 3 – Under IV- Motion – second line delete “self-auditing procedures” – change to “Independent Auditing”.

Page 3 – Second paragraph – 5th sentence delete “and timeline”

Page 5 – Under Board Action – delete “b” from the word legislation

Page 9 – Under #2 – 2nd sentence – change to “repackaging issue

Page 9 – Under #2 – last sentence – change to “at the next Board meeting.”

Motion: Jeanne Furman moved to accept the minutes as amended. Michael Souranis seconded the motion which was approved by the full Board.

III. President/Executive Committee Report

Mr. Levi reported that he and LaVerne Naesea met with Donna Dorsey, Executive Director, Board of Nursing, to introduce himself as the new Board President. He noted

that they discussed the issue of nurses who dispense methadone in Methadone Clinics need for enabling legislation to allow the Practice to Practice. Ms. Dorsey will be sending proposed legislation for the Board's review.

He stated Don Taylor and Ms. Naesea met with Delegate Hammen and discussed upcoming pharmacy issues and trends.

Mr. Levi invited attendees at the Public Meeting to the Board of Pharmacy's Open House on Wednesday, January 17, 2007 from 3:00 pm until 5:00 pm. Mr. Levi also requested Board members to consider changing the August 15th Public and Executive meetings to August 22nd. Jeanne Furman stated that the August 22nd date should not be a problem as long as a room can be reserved. *[A meeting room was subsequently secured. Thus, the date for the August 2007 public and executive meetings are confirmed for August 22, 2007.]*

IV. Executive Director's Report – LaVerne Naesea

Division of Drug Control

Ms. Naesea is anticipating that the Board of Pharmacy will assume the responsibility of conducting pharmacy inspections from Drug Control in the near future. She is awaiting approval from the Deputy Secretaries. She informed the Board about news articles that were published in the Examiner Newspaper and on the news service wire regarding the limited numbers of pharmacy inspections that have been performed in Maryland over recent years.

Revised Inspection Forms Training

Ms. Naesea stated that training for the Division of Drug Control Inspectors on the new Hospital Inspection form is being scheduled in early 2007. Jeanne Furman and Dave Chason will be meeting in the near future to discuss training on the revised hospital inspection form. Ms. Furman recommended that the Board is considering using outside training for sterile compounding forms.

V. PEAC (Pharmacist Education and Assistance Committee) – Dr. Tommasello

Dr. Tommasello reported the following PEAC statistics for the month of November: 12 self-referred pharmacists and 17 Board-referred pharmacists, for a total of: 29 cases.

Dr. Tommasello provided the Board with PEAC's Annual Report for 2006. He distributed and summarized a chart related to cases monitored by PEAC, noting that eleven cases have had no board involvement and that seven of the cases were under PEAC contract before they were brought under board consent. Dr. Tommasello mentioned that at previous meetings the Board had expressed concerns about PEAC's performance and that PEAC took action to address those concerns. Dr. Tommasello reported that the Disciplinary Committee is pleased with PEAC's reports. Dr.

Tommasello feels that PEAC has taken the Board's concerns very seriously and is functioning well. Dr. Tommasello mentioned that the Harbison Group has been contracted to do fundraising for the PEAC Committee and that a campaign entitled "A Bridge to Safety" has been developed. The Harbison Group will be submitting grant requests to various organizations. Dr. Tommasello is confident that the Harbison Group will raise \$10,000. He also noted the "Duty to Report" campaign posters that were provided to all Maryland pharmacies.

PEAC's contract for year 2006 has a one-year option remaining for renewal. The Board voted at a previous public meeting to assume monitoring of pharmacists under Board orders. PEAC will cease monitoring those pharmacists effective January 2nd. The Board will continue to fund PEAC for monitoring and assisting self-referred pharmacists.

VI. Legislation and Regulation Manager Report – Anna Jeffers

Regulations Updates

Pharmacy Technicians- Addition of reinstatement change pursuant to HB 1569

Ms. Jeffers reported that the Board voted in October on proposed regulations for reinstatement of pharmacists whose licenses were revoked under criminal law – Article 5-702. The Board wants the amendment to be submitted at the same time as the amendments to the Pharmacy Technician statute. If the language is not included in the proposal the Board will have to wait until the regulations are effective and completed. The Board plans to include the language in the Pharmacy Technician Proposal under 10.34.01.15.G. The Board voted to approve the inclusion of "reinstatement" language during the October Public Board meeting.

Pharmacist Administration of Influenza Vaccination (fee amendment) – Submitted to the Board of Nursing and the Board of Physicians for Approval

Ms. Jeffers reported that the Board voted last month that the fee that could be charged could not exceed the Medicare Reimbursement rate. The Board also added to the proposed amendments to the regulations that CPR courses have to be given through live instruction. The regulatory proposal is before the Board of Nursing and the Board of Physicians this week. Once comments are received from both Boards, the proposal will be resubmitted.

Legislation

Ms. Jeffers also reported on the language proposed by the Nursing Board to expand nurses' scope of practice to allow dispensing methadone in Methadone Clinics. The draft bill is entitled "State Board of Nursing – Scope of Practice – Dispensing Methadone." The Board amended the proposed language to state "*Registered Nurse or a licensed practical nurse working in a methadone clinic licensed by the Department of Health and Mental Hygiene may dispense methadone in accordance with regulations jointly*"

developed and adopted by the Board of Nursing and the Board of Pharmacy". If acceptable to the Board of Nursing, the language will be implemented in the Nurse Practice Act 8-708.

Motion: Dave Chason moved to accept the proposed language for the draft Bill entitled State Board of Nursing – Scope of Practice – Dispensing Methadone. Donald Taylor seconded the motion.

Board Action: The Board voted unanimously to approve the motion.

Ms. Jeffers stated that she has been in discussion with EHE and HGO about a date for a Wholesale Distributor Educational Briefing. Ms. Jeffers estimated that the briefing will probably be the third or fourth week in January.

Prescription Drug Repository Program Report Approval

Legislation for the Pharmacy Prescription Drug Repository Program requires the Board of Pharmacy to prepare an Annual Report to the Governor and the General Assembly. The report is due January 1st of each year. Legislation has been passed, and regulations have been submitted. The draft Annual Report outlines the three components of the program for which the Board will have administrative oversight. Repositories are allowed to accept, dispense and dispose of drugs that do not meet the criteria of the program. Drop off sites are only allowed to receive and forward drugs to a Board approved Repository. The program is completely voluntary. The regulations are expected to become effective sometime in January.

Motion: Donald Taylor moved to accept the Pharmacy Prescription Drug Repository Program January 1, 2007 Annual Report. David Chason seconded the motion.

Board Action: The Board voted unanimously to approve the motion.

Pharmacy Technician Regulations

Mark Levi directed members to the third page of the revisions to the Pharmacy Technicians prepared regulations in order to address concerns regarding registration of pharmacy students working outside of an Experiential Preceptor Learning program. He asked the Board for a motion to amend the section as follows: Part A. Pharmacy students who are practicing in a pharmacy as part of a school of pharmacy sanctioned experiential learning rotation are not subject to the registration requirements of Regulation .04 of the chapter; Part B. Pharmacy students performing pharmacy technician functions and who are not in a school of pharmacy sanctioned experiential learning program shall: 1) Submit to the Board a signed completed application for exemption from the registration requirements of Regulation .04 of this chapter; and 2) Comply with the following conditions: (a) Provide verification of enrollment and good standing at an accredited school of pharmacy; b) Pay a fee as set forth in COMAR 10.34.09; and c) Submit a request for a State Criminal History Records check 3) A

pharmacy student may not begin work under this exemption until they have received notice that the Board has granted the exemption.

Anna Jeffers stated that there is a reinstatement fee but no exemption fee. Ms. Jeffers will include in the regulations that there will be an exemption fee to students that meet the criteria.

Motion: Michael Souranis moved to accept the amendments to the Pharmacy Technician proposed regulations. David Chason seconded the motion.

Board Action: The Board voted unanimously to approve the motion.

Discussion were held and several points were clarified. 1. The experiential part of the program is not to exceed six months. 2. A task force will not be established to revise components of the regulations. Responses included the following: Training Programs are not to exceed six months and a task force will not be established to revise components of the regulations. Mr. Levi stated that time is an issue and the prepared regulations need to be moved along in order to meet statutory requirements. Jeanne Furman suggested that students apply yearly to demonstrate that they are still enrolled in a school of pharmacy and to continue their exemption; also that a nominal exemption application fee be charged.

Board Action: The Board voted unanimously to approve the motion.

There was discussion whether students should be allowed to work during the period that they are waiting for a response from the Board to their exemption applications.

Motion: Joseph DeMino moved that students be allowed to work as Pharmacy Technicians at the time of application. Harry Finke, Jr. seconded the motion.

Board Action: Mark Levi, Donald Taylor, Joe DeMino, Mike Souranis, Rodney Taylor, Jeanne Furman, Cindy Anderson, Alland Leandre, Margie Anne Bonnett, Harry Finke, Jr. and Mayer handelman opposed the approved motion. Dave Chason voted to support the motion.

Motion: Don Taylor moved that students provide annual proof of enrollment in good standing at a School of Pharmacy and that they pay a nominal fee annually.

Board Action: The Board voted to approve the motion. Rodney Taylor opposed the motion.

VII. Administration and Public Support – Patricia Gaither

Personnel Update

Ms. Gaither reported that Alicia Carter, Executive Secretary, would have permanent employee status, effective December 20th. Briget Melvin, Secretary/Receptionist received regular contractual employee status, effective December 15th. The interviewing process will be completed for the Database Officer position in the MIS Unit following two final interviews scheduled in late December 2006. A tentative selection has been made for the Administrative Specialist position that is vacant in the Licensing Unit.

Seven resumes for the Compliance Officer position have been approved by the Department and submitted to the Board for consideration. Interviews for that position will be scheduled during the first two weeks of January. The Administrator Specialist II position that will work with pharmacists under Board orders has been re-classed to Coordinator of Special Programs/Health Services II. Ms. Gaither has completed and submitted paperwork to the Department of Personnel in order to initiate the recruitment process. Receipt of feedback from the Department of Personnel on the re-classification for the Administrative Legislative Officer II position is still pending. Ms. Gaither stated she plans to follow-up on the request. All positions are expected to be filled by March 30, 2007.

Public Information Officer Report - Summar Goodman

Ms. Goodman stated that she is revising the Board's brochures. She plans to have the brochures completed and the Annual Report prepared by the time of the January 17th Open House.

VIII. Management Information Services – Tamarra Banks

Statistics

Ms. Banks reported the November statistics: 7904 active pharmacists, of which 5,422 practice in Maryland; 1,637 total pharmacies, of which 1,242 are located in Maryland and 395 non-resident pharmacies, 832 total distributors, of which 192 are in Maryland and 639 non-resident distributors. Establishment Renewals: 1,401 renewed pharmacies for 2007 – 85%, 464 renewed distributors for 2007 – 55%. Only 22 chain stores and 5 hospital pharmacies were not renewed.

RESI/Towson University

Leslie Pachol provided the Board with an update on the In-House Database Development Project. Ms. Pachol stated that she has met with LaVerne Naesea and staff to get recommendations about streamlining the systems. Ms. Pachol disseminated a written presentation outlining what RESI plans to accomplish if allowed to complete the contracted project, specifically: contracting with RESI will ensure improved services, customized tracking, customized reports, enhanced communications between licensing & disciplinary units, detailed tracking of establishment ownership information, implementation of a logical and efficient database structure, total control of functions for future enhancements, and total ownership of the MIS system. Ms. Naesea stated that

Secretary Van Mitchell had negotiated a deal with License 2000 contractors and met with the Boards/Commissions on December 4th to encourage them to contract with that contractor (License 2000). Since the Board of Pharmacy had already entered into a contract with RESI/Towson University, she recommended that the contract with RESI/Towson University be continued. Ms. Banks stated that the initial contract cost was \$81,000; however because RESI/Towson supported the Board during the period that the Board's Database Specialist has been vacant and there were other major necessary amendments to the scope of work, at least an additional \$80,000 would be required in order to complete the project.

Motion: Jeanne Furman moved that the Board amend the contract with RESI/Towson University for up to an additional \$100,000. Donald Taylor seconded the motion.

Board Action: The Board voted unanimously to approve the motion.

Personnel

Ms. Banks reported that 8 applicants were selected to interview for the Database Specialist position. The Database Specialist Search Committee interviewed 2 candidates and an additional 2 candidates are scheduled to interview Friday, December 22, 2006.

Emergency Preparedness

Ms. Banks reported that MIS has been assisting the Emergency Preparedness Committee efforts in renewing the Pharmacist Volunteer badges. The new badges will display the original issue date, with no expiration. She also reported that MIS is working on a new homepage that features a message from the Executive Director; Board headings at the top; and a scroll down for links to new information from the Board. License numbers have been added to the verification page as per the Licensing Committee. The license issue dates have been removed from the scores page and a notation as to whether the license has been issued will replace that information. This will insure the confidentiality of scores. Personal computers have been ordered for some staff members and should arrive in late December 2006. Laptops still need to be returned by a few former Board members. Ms. Banks plans to contact those members to schedule a time to have their laptops returned to the Board's office.

Other News/Events

Ms. Banks informed the Board that FDA is pushing to use manufacturers/distributors RFID (Radio Frequency Identification) technology.

IX. Committee Reports

A. Licensing Committee – Mike Souranis

Statistics – Mr. Souranis reviewed the November statistics.

The quarterly review of assisting residents who are actually taking nine or more meds and have three or more active disease states and that are being treated will have a quarterly review by a registered pharmacist preferably onsite.

Ms. Banks stated that pharmacies are not allowed to pay on line with credit cards because the Board would have to pay for the additional service.

Motion: Joe DeMino moved that the system be updated to add credit card payments as a method to make payment of fees easier for renewing pharmacies. Donald Taylor seconded the motion.

Board Action: The Board voted unanimously to approve the motion.

A suggestion was made to the Licensing Unit that it should implement an on-line check-off box where renewing pharmacists could attest that they completed required CEs. The Board requires pharmacists to write their ACPE or Maryland numbers. It was that it be put in front of a license number of pharmacists certified to administer influenza vaccines. It was suggested that it be put in front of a license number of pharmacists certified to administer influenza vaccines. The Board will try to accommodate that request.

Influenza Administration – Permit Holder Approval – Shirley Costley

A letter was sent to the Board by Anthony Brooks of the National Institute of Health with asking should an applicant that is employed with NIH (National Institute of Health) need to be registered with the Board if he is not administering the vaccine outside of NIH? It was explained that the regulations state there must be an agreement with Permit Holder in order to administer the vaccine. Ms. Costley asked for advisement from the Board as to how to proceed. Mr. Levi stated that Licensing should write back to the National Institute of Health informing the pharmacist that if he wants to make application to administer the Influenza vaccine he should obtain a Permit Holder.

Sub-committee recommendations regarding review of exams, programs, pharmacy students requirements and criminal background check and approval process.

Mr. Taylor reported that the sub-committee formed a process for the process for technician program approvals. After substantial discussion and advice from Board Counsel, it was determined that specific written criteria should not be used to guide evaluation of programs. The regulations would have to be amended to reflect everything that would be considered in a training program that is not currently in the current regulations.

B. Practice Committee – Dave Chason

1. Constituent Questions and Responses

- a. Gary Hollenbeck – UPM Pharmaceuticals, Inc.

As a pharmaceutical research and development company, can we buy prescription drug products, for legitimate product development and testing purposes, without a prescription?

Board Action: The Board voted unanimously to table the response letter until the Practice Committee developed a recommended response based on discussions held at the meeting.

- b. Tim Koch - Wal-Mart

Utilization of central processing [workload balancing] technology – Is Central Processing allowed? In what facilities will this be acceptable to the Board? In-state, out-of-state, and home? Are there Laws/Regs in Maryland that govern this practice? What special requirements, if any would have to be met? Does the facility/home have to be permitted? For out-of-state processing, does the individual performing the Central Processing have to be permitted in-state?

Motion: Jeanne Furman moved to accept the Practice Committee's letter as amended to indicate that Location B may be a Maryland licensed pharmacy with a licensed pharmacy, licensed in the state they are performing data entry. Harry Finke, Jr. seconded the motion.

Board Action: The Board voted unanimously to accept the motion.

2. Approval of Letter to the Board of Physicians requesting clarification of the various formats for prescriptions and physician signature options.

Motion: Donald Taylor moved to amend letter to the Board of Physicians to include that signatures have to be faxed on control substances #3, 34, and #5.

Board Action: Board voted unanimously to approve the motion.

3. Long Term Care Task Force – Mayer Handelman

Assisted Living Regulations

Mayer Handelman reported that the Long Term Care Task Force has been working with the Office of Health Care Quality on Assisted Living Regulations. The Office of Health Care Quality suggested that the Task Force follow a medication management process that would require a quarterly review. The review can be done by a nurse or physician. A licensed pharmacist could also do the review.

Skilled Nursing Facilities

The quarterly review of assisting residents who are actually taking nine or more meds and have three more active diseased states that are being treated will have a quarterly review by a registered pharmacist preferably on-site.

There was some discussion on Repackaging. The committee decided not to recommend allowing repackaging in the State of Maryland.

Mr. Handelman referred to the letter from NABP to the Honorable Jacob D. Corman from the state of Pennsylvania concerning their opposition to H.B. 1022, the Long Term Care Patient Access to Pharmaceuticals Act. NABP responded that it believes the repackaging practices mandated by this legislation are clearly in opposition to most, if not all, state prescription medication dispensing laws and may cause a danger to patients' safety.

The meeting was adjourned 12:21 pm

